

REMARKS

Reconsideration is respectfully requested in light of the amendments above and the remarks that follow.

Claims 1-2, 9-10, and 15-18 are pending. Claims 3-6 and 11-14 are withdrawn. Claims 7 and 8 have been canceled. Claims 1, 9, and 10 have been amended. Support for amended claim 1 is found, for example, in chemical structures 4 and 5, following paragraph [0076] of the specification as filed. Applicant notes that the amendment to claim 1 is made to rectify a republication error on the part of the U.S. Patent and Trademark Office, as discussed in Applicant's paper submitted on July 7, 2008. Support for amended claims 9 and 10 is found, for example, in paragraphs [0011], [0012], and [0014] and claims 7 and 8 of the specification as filed. Claims 15-18 are new. Support for new claims 15-17 is found, for example, in paragraphs [00076] and [00077] and the chemical structures and reaction schemes presented below these paragraphs in the specification as filed. Support for new claim 18 is found, for example, in paragraph [0020] of the specification as filed.

The Examiner states on page 2 of the Office Action that Applicant's argument submitted with the Reply filed on July 7, 2008 is persuasive, but that, nevertheless, the sets of claims identified as Group I (claims 1-2 and 7-10), Group II (claims 3-6), and Group III (claims 11-14) lack unity and, therefore, are restricted.

Applicants argue that restriction is improper, because claims of Groups I, II, and III possess unity of invention by virtue of sharing the special technical feature of the compound presented in claim 1. The thiohydantoin compound presented in claim 1 has not been shown in the prior art and, therefore, is a special technical feature, as conceded by the Examiner in the paragraph bridging pages 4 and 5 of the Office Action. Claims 3-6 of Group II, each of which depends from claim 1, share this special technical feature, in that each of these claims include the step of contacting a prostate cancer cell with the compound of claim 1. Claims 13-14 of Group III share the same special technical feature of claim 1, in that each of these claims include a method of making the compound presented in claim 1.

The Examiner notes on page 5 that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are

drawn only to one of the combinations of categories enumerated in 37 CFR 1.475(b). In the present application, claims of Groups I, II, and III represent the combination (3) of 37 CFR 1.475(b): "A product, a process specially adapted for the manufacture of said product, and a use of said product." That is, claims 1-2 of Group I are drawn to a product, i.e., the compound presented in claim 1; claims 3-6 of Group II are drawn to a use of the product, i.e., contacting a prostate cancer cell with the compound presented in claim 1; and claims 13-14 of Group III are drawn to a process specially adapted for the manufacture of said product, i.e., a method for making the compound presented in claim 1. Applicants note that under the unity of invention standard, the expression "specially adapted" does not require that the product could not also be manufactured by a different process than the one claimed. See, MPEP 1893.03(d). Therefore, Applicants respectfully request that the Examiner withdraw the finding of lack of unity and requirement for restriction among Groups I, II, and III, and examine all of claims 1-6 and 9-18 in this application.

Claims 1-2 and 7-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,656,651 to Sovak et al. (herein, "Sovak"), in view of U.S. Patent No. 6,949,521 to Chu et al. (herein, "Chu"). Applicant respectfully traverses.

The content of claims 7 and 8 has been incorporated into claims 9 and 10, respectively. Claims 7 and 8 have been canceled, rendering their rejection moot.

On page 10 of the Office Action, the Examiner concedes that Sovak does not teach the compound claimed in the instant application wherein the N substitution is $(CH_2)_nN_3$ with $n = 3-8$ or $C_6H_4N_3$.

On page 10 of the Office Action, the Examiner indicates that Chu teaches prodrug compositions comprising azide derivatives of drugs. However, Chu teaches nothing pertinent to Sovak or the compounds of the present claims. All of the specific examples of prodrug compositions presented in the written description of Chu include a nucleobase group with the azide group bound to the 6-position (adjacent to the set of nitrogen-carbon-nitrogen atoms) of the pyrimidine ring of a purine group or to the corresponding 4-position (adjacent to the set of nitrogen-carbon-nitrogen atoms) of a pyrimidine group of the nucleobase. See, e.g., Scheme 1 (col. 7), Schemes 2-3 (col. 8), Schemes 4-5 (cols. 13-14), Schemes 6-7 (cols. 15-16), Schemes 8-

10 (cols. 17-18), Scheme 12 (cols. 19-22), Scheme 13 (col. 25), Scheme 14 (col. 26), Scheme 15 (cols. 33-34), and Scheme 16 (col. 37) of Chu.

The compounds claimed in Chu are further limited to those which have an azide substituted on the 6-carbon of a purine group. For example, Chu's independent claim 1 is limited to an "azide derivative of a drug ... wherein said drug is a biologically active therapeutic purine compound or a purine nucleoside or purine nucleotide compound and said azide group occurs on the 6-position of said purine compound or said purine nucleoside or nucleotide compound."

The metabolism of nucleotides referred to by Chu would not be relevant to the compounds of Sovak and has no bearing on the very different hydantoin compounds claimed here. The Sovak compounds are not presented as drugs for which prodrugs would be desirable. To the contrary, column 3, lines 42-52 of Sovak indicate that compounds with substituted amines are favored; an azide modification could not serve as a prodrug for such compounds.

Chu makes no mention of any hydantoin compounds or hydantoin derivatives, such as thiohydantoin. No mention is made of any advantage obtained by functionalizing a hydantoin compound or derivative with an azide group. Nothing like the claimed compounds or how to make them is presented.

The activity of compounds according to the invention and of the prior art is unpredictable, and a person of ordinary skill would not have expected the desirable activity of the claimed compounds. In particular, the anti-prostate cancer efficacy of the claimed compounds is a surprising and unpredictable advantage that is not obvious in the cited references.

Consequently, one of ordinary skill in the art would not have been motivated to combine the teachings of Chu with the teachings of Sovak to make an azide-functionalized mono- or diarylhydantoin compound, such as claimed in claims 1, 2, 9, and 10 of the present application. Thus, the Examiner has not made out a *prima facie* case of obviousness and Applicant respectfully requests that the rejection of claims 1, 2, 9, and 10 be withdrawn.

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Applicant maintains that, for the reasons given above, the finding of lack of unity and requirement for restriction among claims of the present application should be withdrawn. Applicant further maintain that all pending and presently withdrawn claims, claims 1-6 and 9-18 are patentable and that, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Applicants respectfully request that a Notice of Allowance of all pending claims not withdrawn, claims 1-6 and 9-18, be timely issued in this case.

Respectfully submitted,



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